NOV - 7 2003

# Summary of 510(k) Submission for Mission ISE Reference & $CO_2$ Reagents for Beckman Synchron Delta & CX® Systems

1. **Submitter's Name & Address**

Mission Diagnostics
331 Fiske St
Holliston MA 01746
FAX: 508-429-0452

**Contact Person:**
Linda Stundtner
QA/RA Manager
508-429-0450

Establishment Registration Number: 3003656721

Date of Preparation: Sept 22, 2002

2. **Identification of the Device:**

| | |
|---|---|
| Proprietary/Trade name: | Calibrating Material, Reference Buffer |
| Common or usual name | Calibrators for ISE automated systems |
| Classification name: | Calibrator, secondary |
| Device Classification | II |
| Regulation Number: | 21 CFR § 862.1150 |
| Panel: | Chemistry (75) |
| Product Code: | JIT |

- Mission manufactures calibrators intended to serve as direct replacements to like named products (predicate devices) manufactured by Original Equipment Manufactures (OEM)

3. **Predicate Device:**

- Mission claims substantial equivalence to the OEM Materials listed below:

**Substantial Equivalence Table of Product PN's & Trade Names**

| Mission Product | | OEM Equivalent | |
|---|---|---|---|
| BK-443320D | CO2 Alkaline Buffer | 443320 | CO2 Alkaline Buffer |
| BK-443330D | CO2 Acid | 443330 | CO2 Acid |
| BK-450214D | ISE Electrolyte Reference | 450214 | ISE Electrolyte Reference |

- The predicate reagents are encompassed in the 510(k)'s K942676 & K864236 cleared 11/02/1994 & 12/31/1986 respectively.

4. **Device Description:**

- The Calibrators for the OEM Instruments are aqueous reagents with salts added to obtain desired analyte levels to provide calibration of the electrodes.

- **Intended Use:**

- The reagents are intended for use on equivalent OEM Instruments.

- The original equipment manufacturer (OEM) of the instruments and the predicate reagents are necessary for the continued operation and use of the instruments.

- Mission uses a similar composition, description and packaging as that used by the OEM in its products, as shown in the packaging section of this submission.

- Performance equivalence is shown in the following manner:

  - Through a method comparison where results obtained on an equivalent OEM analyzer, calibrated with Mission calibrating material are compared with results obtained on the same analyzer calibrated with OEM calibrating material.

  - A summary of the results of these studies follows:

## 5. Performance Characteristics:

Precision and correlation data are collected per:
- SOP23-01-02 Performance Study Protocol for 510(k) Submission
- Data for each instrument and each run are recorded on SOP23-03F Performance Study Record Sheet. (See Attachment Section for Copy of Procedures)

All analytes tested passed criteria per SOP23-01-02 Performance Study Protocol for 510(k) Submission and performed equally to the OEM.

Testing was performed on CX® Delta and CX® depending on availability.

### Table of Precision of Serum Controls, CSF Controls & Urine Controls on CX® Delta

| Analyte | Level | N | Mean | Sd | Min | Max | %CV |
|---|---|---|---|---|---|---|---|
| Na mmol/L | DCtrol 1 | 43 | 142.0 | 6.4 | 129.6 | 157.0 | 4.5 |
| | DCtrol 2 | 38 | 155.7 | 6.9 | 148.7 | 174.4 | 4.4 |
| K mmol/L | DCtrol 1 | 43 | 4.22 | 0.22 | 3.88 | 4.71 | 5.10 |
| | DCtrol 2 | 45 | 8.10 | 0.37 | 7.69 | 9.21 | 4.59 |
| Cl mmol/L | DCtrol 1 | 43 | 107 | 5 | 98 | 118 | 4 |
| | DCtrol 2 | 38 | 118 | 5 | 113 | 131 | 4 |
| Ca mmol/L | DCtrol 1 | 31 | 2.51 | 0.08 | 2.39 | 2.69 | 3.06 |
| | DCtrol 2 | 27 | 3.35 | 0.18 | 3.16 | 4.00 | 5.23 |
| $CO_2$ mmol/L | DCtrol 1 | 40 | 14.8 | 0.7 | 13.1 | 16.0 | 4.4 |
| | DCtrol 2 | 43 | 25.4 | 1.1 | 23.1 | 28.2 | 4.2 |
| Na mmol/L | CSF 1 | 13 | 127.4 | 6 | 119.4 | 139.0 | 3.8 |
| | CSF 2 | 12 | 159.9 | 5 | 153.8 | 170.3 | 4.9 |
| Cl mmol/L | CSF 1 | 13 | 89 | 4 | 84 | 95 | 4 |
| | CSF 2 | 12 | 105 | 3 | 102 | 111 | 3 |
| Na mmol/L | URINE 1 | 48 | 65.6 | 4.9 | 59.7 | 77.0 | 7.5 |
| | URINE 2 | 44 | 208.2 | 7.9 | 197.1 | 227.8 | 3.8 |
| K mmol/L | URINE 1 | 48 | 33.7 | 2.2 | 31.5 | 39.0 | 6.4 |
| | URINE 2 | 45 | 108.4 | 6.1 | 101.4 | 122.9 | 5.6 |
| Cl mmol/L | URINE 1 | 47 | 100 | 6 | 92 | 113 | 6 |
| | URINE 2 | 47 | 256 | 10 | 245 | 280 | 4 |
| Ca mmol/L | URINE 1 | 29 | 1.57 | 0.14 | 1.44 | 1.90 | 8.97 |
| | URINE 2 | 32 | 3.50 | 0.14 | 3.27 | 3.84 | 3.99 |

## Table of Precision of Serum Samples on CX® Delta

| Analyte | Level | N | Mean | Sd | Min | Max | %CV |
|---|---|---|---|---|---|---|---|
| Ca mmol/L | Normal | 18 | 2.42 | 0.06 | 2.30 | 2.52 | 2.5 |
| | Lo | 18 | 1.96 | 0.06 | 1.86 | 2.05 | 3.1 |
| | High | 18 | 3.65 | 0.13 | 3.47 | 3.84 | 3.6 |

## Table of Precision of Serum Controls on CX®

| Analyte | Level | N | Mean | Sd | Min | Max | %CV |
|---|---|---|---|---|---|---|---|
| Na mmol/L | DCtrol 1 | 18 | 139.7 | 0.08 | 138.5 | 141.1 | 0.6 |
| | DCtrol 2 | 18 | 154.1 | 1.03 | 152.6 | 156.0 | 0.7 |
| K mmol/L | DCtrol 1 | 14 | 4.07 | 0.01 | 4.05 | 4.08 | 0.29 |
| | DCtrol 2 | 12 | 7.36 | 0.03 | 7.89 | 7.98 | 0.42 |
| Cl mmol/L | DCtrol 1 | 18 | 104 | 0.5 | 103 | 105 | 0.5 |
| | DCtrol 2 | 18 | 118 | 0.8 | 116 | 120 | 0.7 |
| $CO_2$ mmol/L | DCtrol 1 | 18 | 14.8 | 0.2 | 114.4 | 15.1 | 1.4 |
| | DCtrol 2 | 18 | 26.5 | 0.3 | 25.7 | 27.1 | 1.3 |

## Table of Correlation – Serum Values on CX®

| Analyte | N | Slope | Intercept | $R^2$ | Range |
|---|---|---|---|---|---|
| Na | 62 | 0.95 | 3.59 | >0.99 | 95.4 – 203.4 |
| K | 91 | 0.99 | -0.03 | >0.99 | 1.81 – 8.79 |
| Cl | 76 | 0.97 | 1.49 | >0.99 | 54 – 203 |
| $CO_2$ | 76 | 0.93 | 1.58 | >0.99 | 8 – 30.7 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 7 2003

Diamond Diagnostics, Inc.
c/o Ms. Linda M. Stundtner
QA/RA Manager
Mission Diagnostics
331 Fiske Street
Holliston, MA 01746

Re: k033061
Trade/Device Name: Mission Diagnostic ISE Reference & CO2 Reagents for Beckman Synchron Delta & CX® Systems
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: September 22, 2003
Received: September 29, 2003

Dear Ms. Stundtner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k( Number K033061

Device Name:
Mission Diagnostic ISE Reference & CO2 Reagents for Beckman Synchron Delta & CX® Systems

**Indication For Use:**

- The three products encompassed by this request are intended for in-vitro diagnostics use.

| Mission Product | |
|---|---|
| BK-443320D | CO2 Alkaline Buffer |
| BK-443330D | CO2 Acid |
| BK-450214D | ISE Electrolyte Reference |

- Mission Electrolyte Reference Reagent provides reference points for Na, K, Cl, Ca (on Delta's only) and TCO2. When used in conjunction with $CO_2$ Acid Reagent, $CO_2$ Alkaline Buffer and Electrolyte Buffer, the ISE Electrolyte Reference is used for the calibration of the ISE electrodes; sodium, potassium chloride and calcium (on Delta's only) and CO2.
- The CO2 Acid reagent is used to release CO2 from samples
- The CO2 Alkaline in used to provide a constant CO2 concentration as reference for the CO2 electrode.
- Mission reagents are intended to serve as direct replacements to the predicate devices manufactured by the OEM.
- The products encompassed are to be handled using normal laboratory precautions.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrance of CDRH, Office of the Device Evaluation (ODE)

Carol Benson for Jean Cooper, OVM
**Division Sign-Off**

**Office of In Vitro Diagnostic Device Evaluation and Safety**

**510(k)** K033061

(Optional format 3-10-98)